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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,176	03/09/2006	Graham Edmund Kelly		8060

23373 7590 05/12/2009

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EXAMINER	
PACKARD, BENJAMIN J	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
05/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,176	KELLY, GRAHAM EDMUND	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10,13,23,24 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10,13,23,24 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 10/530,176, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

The disclosure is objected to because of the following informalities: It appears at page 38, lines 20-27, the description of *in vivo* treatment appears to uses the word “pH” instead of the prior word “dehydroequol” or “DHE” (as used in the figures). For purposes of Examination, it will be presumed the words are mixed, given pH is not a composition which is administered, but a property of a composition.

Appropriate correction is required.

Drawings

The drawings are objected to because Figure 8 includes the label of administration of Ph, which appears to be an error, given the other figures disclose the administration of “DHE”. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If

a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112 – New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-10, 23, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The addition of the chemotherapeutic agents as an "anti-mitotic agent" is not supported by the original disclosure. While the specification discloses adrenal corticosteroids have the ability to inhibit mitotic divisions (pg 26 lines 12-15), this single specie does not provide written

support for the broader genus of mitotic agents. Similarly, claim 26 is directed to cancer cells and tumors are/is "hormone-responsive." The only disclosure directed to hormone responsiveness is at pg 26 lines 17-19, which describes certain hormone antagonists used to treat prostate cancer, but the disclosure does not suggest treating hormone-responsive cancer cells and tumors.

Claim Rejections - 35 USC § 112 - Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-10, 13, and 26-28 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cisplatin – resistant ovarian cancer of cell lines CP70 and A2780 in vivo, as well as treating cell lines shown in talbe 1 HPAC, PC3, and DU145 in vitro, with dehydroequol and cisplatin, does not reasonably provide enablement for increasing the sensitivity of cancer cells or tumors to a chemotherapeutic agent in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants assert that by narrowing the claims to two general formulae (VI) and (VII) and limiting the chemotherapeutic agents to platinum-based agents or an anti-mitotic agent the breadth of the claims is reduced and Examples 1 and 2 demonstrate

how the recited compounds can be used to increase the sensitivity of various cancer cell lines to the recited chemotherapeutic agents.

First, the evidence presented by applicant in Example 1 demonstrates the ability to increase the effect of dehydroequol and Cisplatin in the cell lines of Table 1 (pg 37). It is unclear if this is due to an “increased sensitivity” to the chemotherapeutic agent or simply unexpected results. Regardless, the disclosure is not commiserate in scope of the claims and where the art is considered unpredictable, as discussed in the Action dated 08/04/08, one of ordinary skill would not accept the assertion that one combination would provide reasonable expectation of success for the broader claimed combinations on cancer cells generally.

Second, while Example II of the instant specification provides some evidence that c cisplatin –resistant ovarian cancer of cell lines CP70 and A2780 in vivo, as well as treating cell lines shown in talbe 1 HPAC, PC3, and DU145 in vitro, may be sensitized to the resistant chemotherapeutic agent by pretreatment of dehydroequol, this disclosure again does not support the broader class of compounds of formula (VI) or (VII) or the broader class of cancer cells or tumors treatable, generally.

Finally, Examiner wishes to point out that instant claim 10 is directed to combination therapy after observance of resistance to a chemotherapeutic agent. Where the resistance is not directed to "the chemotherapeutic agent", it would be obvious that cancer cells and tumors would be resistant to some chemotherapeutic agents, and not others.

Claim Rejections - 35 USC § 103

Claims 1, 3-4, 6-10, 13, 23-24, and 26-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al (WO98/008503) in view of Ekwurlbe et al (US 6,380,405).

Applicants assert In re Kerkhoven is not applicable because unexpected results are shown when dehydroequol and cisplatin are used together. Additionally, Applicants assert the prior art fails to teach an increased sensitivity of cancer cell or a tumor to a chemotherapeutic agent.

As discussed above, the showing of unexpected results is not commiserate in scope with the claims and therefore does not provide sufficient evidence to overcome the instant rejection. Further, while the instant claims are directed to “increasing the sensitivity of cancer cells or a tumour to a chemotherapeutic agent", the method appears to be met where it would reasonably be expected to flow from treating a cancer patient where administration of the same compounds is given to the same patient population (i.e. dehydroequol and cisplatin are administered to ovarian cells or patients with ovarian cancer).

Obvious-Type Double Patenting

Claims 1, 3-4, 6-13, and 23-28 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-21 of U.S. Patent No. 6,649,648 in view of Ekwurlbe et al (US 6,380,405).

As discussed above, the asserted unexpected superior results is not commiserate in scope of the instant claims and therefore not sufficient to overcome the rejection.

Claims 1, 3-4, 6-13, and 23-25 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-38 of copending Application No. 10/547,077 in view of Ekwurlbe et al (US 6,380,405).

As discussed above, the asserted unexpected superior results is not commiserate in scope of the instant claims and therefore not sufficient to overcome the rejection.

Status of Claims

Claim 2 requires prior to contacting cancer cells or tumor were/was not sensitive to the agent, which would not be an obvious in light of the prior art, as there would not be an expectation of success that a compound-resistant cell line would be sensitive to the resistant compound after application of another compound. This claim differs from claim 10 in that "the chemotherapeutic agent" is the agent of claim 1, but claim 10 only requires resistance to "a chemotherapeutic agent", which does not have to be the agent of claim 1.

Note, while claim 2 appears to be free of the prior art, only cisplatin –resistant ovarian cancer of cell lines CP70 and A2780 in vivo, as well as treating cell lines shown

in talbe 1 HPAC, PC3, and DU145 in vitro, appear to be enabled for treatment with the elected combination of cisplatin in combination with dehydroequol.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612